

REMARKS

The present application has been reviewed in light of the Final Office Action mailed October 26, 2006. Claims 1-78 are currently pending, claim 1 having been previously amended, and claims 25-77 having been previously withdrawn. Applicants reserve the right to present previously withdrawn claims 25-77 in a divisional application. Reconsideration of the present application, as amended, is respectfully requested in view of the following remarks.

1. Rejections under 35 U.S.C. S 103

Claims 1-16 and 19-24 were rejected under 35 U.S.C. §103(a) as being unpatentable over Storm (U.S. Patent 4,140,130) in view of Edwards (U.S. Patent 5,964,755) and further in view of Gough et al. (U.S. Patent 5,951,547) and even further in view of Rudie et al. (U.S. Patent 6,496,737).

Applicants submit that claim 1, as previously amended, is allowable over Storm '130 in view of Edwards '755 and further in view of Gough et al '547 and even further in view of Rudie et al. '737 because Storm '130, taken alone or in any proper combination with Edwards '755 and/or Gough et al. '547 and/or Rudie et al. 737, does not teach or suggest previously amended independent claim 1.

Claim 18 was rejected under 35 U.S.C. §103(a) as being unpatentable over Storm '130 in view of Edwards '755 and further in view of Gough et al. '547 and even further in view of Uthe (U.S. Patent 5,829,519) and further in view of Rudie et al. '737.

Applicants submit that claim 18 is dependant on claim 1, and that claim 1, as previously amended, is allowable over Storm '130 in view of Edwards '755 and further in view of Gough et al '547 and even further in view of Uthe '519 and even further in view of Rudie et al. '737 because Storm '130, taken alone or in any combination with Edwards '755 and/or Gough et al. '547 and/or Uthe '519 and/or Rudie et al. 737, does not teach or suggest previously amended independent claim 1.

Claim 17 was rejected under 35 U.S.C. §103(a) as being unpatentable over Storm '130 in view of Edwards '755 and further in view of Gough et al. '547 and even further in view of Edwards (U.S. Patent 5,281,217) and further in view of Rudie et al. '737.

Applicants submit that Claim 17 is dependant on claim 1, and that claim 1, as previously amended, is allowable over Storm '130 in view of Edwards '755 and further in view of Gough et al '547 and even further in view of Edwards '217 and even further in view of Rudie et al. '737 because Storm '130, taken alone or in any combination with Edwards '755 and/or Gough et al. '547 and/or Edwards '217 and/or Rudie et al. 737, does not teach or suggest previously amended independent claim 1.

2. Discussion Regarding Independent Claim 1

Independent claim 1, as previously amended, recites a cooling system for use with a microwave antenna, including, *inter alia*, a cooling jacket adapted to at least partially surround a microwave antenna and defining a fluid channel around at least a portion of the microwave antenna, wherein the cooling jacket is further adapted to circulate a cooling fluid through the

fluid channel such that at least a portion of the microwave antenna is in direct fluid contact with the cooling fluid and wherein the microwave antenna comprises a distal tip configured to be advanced percutaneously through tissue.

According to the present disclosure and as seen in FIGS. 4A-4E, “[a]ntenna cooling assembly 100 may generally comprise a cooling handle assembly 102 and an elongate outer jacket 108 extending from handle assembly 102. Microwave antenna 104 may be positioned within handle assembly 102 such that the radiating portion 106 of antenna 104 extends distally into outer jacket 108 towards tip 110.” (see para. [0066]). “Fluid entering handle body 112 may come into direct contact with at least a portion of the shaft of antenna 104 to allow for convective cooling of the antenna shaft to occur.” (see para. [0068]). “The cooling fluid may enter fluid channel 134 and fill the volume surrounding at least a portion of the antenna 104.” (see para. [0069]).

3. Legal Standard for Obviousness

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant’s disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

More specifically on the third prong of establishing a *prima facie* case of obviousness, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or modification to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. “The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art.” *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). See also *In re Lee*, 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) (discussing the importance of relying on objective evidence and making specific factual findings with respect to the motivation to combine references); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

While Applicants do not concede that factual support has been established for supporting a rejection for the claimed invention, if the Examiner determines there is factual support for rejecting the claimed invention under 35 U.S.C. §103(a), the Examiner must then consider any evidence supporting the patentability of the claimed invention, such as any evidence in the specification or any other evidence submitted by the Applicant. The ultimate determination of patentability is based on the entire record, by a preponderance of evidence, with due consideration to the persuasiveness of any arguments and any secondary evidence. *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). The legal standard of “a preponderance of evidence” requires the evidence to be more convincing than the evidence which is offered in opposition to it. With regard to rejections under 35 U.S.C. §103(a), the Examiner must provide

evidence which as a whole shows that the legal determination sought to be proved (i.e., the reference teachings establish a prima facie case of obviousness) is more probable than not.

4. Discussion of References Cited by Examiner

In rejecting independent claim 1 under 35 U.S.C. §103(a) as being unpatentable, the Examiner cites and combines at least four (4) references, namely, Storm '130, Edwards '755, Gough et al '547 and Rudie et al. '737. Applicants respectfully submit that such a rejection is improper or tenuous at best since the combination of said references fails to render claim 1 obvious. Accordingly, Applicants respectfully submit that the rejection of claim 1 under 35 U.S.C. §103(a), as being unpatentable over Storm '130 in view of Edwards '755 and further in view of Gough et al '547 and even further in view of Rudie et al. '737, should be withdrawn.

a. U.S. Patent No. 4,140,130 to Storm

Storm '130 discloses electrode means or structures 72 or 90 for electromagnetic radiational heating of tumor bearing tissue. The electrode means 72 or 90 are configured and adapted for **placement on an outer surface of the tissue** of the patient. A cooling chamber means 74 is applied to the back side of an emitting surface 71 of the electrode means 72 or 90. The electrode means 72 or 90, as illustrated in FIGS. 1 and 2, covers an outer portion of the patient's skin (e.g., the thigh) with emitting surface 71. According to Storm '130, "[s]ecurement means for the electrode means 72 may include a strap or other suitable holding means for maintaining the emitting surface 71 in direct contact with the body portion being treated." (see Col. 11, lines 61-64).

Storm '130 does not disclose a fluid channel around the antenna or fluid in direct contact with the microwave antenna, as called for in claim 1.

b. U.S. Patent 5,964,755 to Edwards

Edwards '755 discloses an ablation apparatus including, *inter alia*, an expandable member 12 that is introduced into a desired body organ or lumen through an introducer sleeve 14. (see Col. 4, lines 1 and 2). "Following introduction, introducer sleeve is withdrawn and can be retracted into handle." (see Col. 4, line 34-36; and Col. 5, line 10.) After withdrawing the introducer sleeve, expandable member 12 is filled with fluid causing it to be distended and therefore retained in position. (see Col. 4, line 24-25; and Col. 5, line 15-18).

Edwards '755 does not disclose a fluid channel around the antenna, as called for in claim 1.

c. U.S. Patent 5,951,547 to Gough et al.

Gough et al. '547 discloses an RF (radio frequency) ablation treatment apparatus 10 including, *inter alia*, a multiple antenna device 12 having a primary antenna 14 with a central lumen and a distal end, and a secondary antenna 16 slidably positioned within the central lumen of the primary antenna and deployable therefrom.

The structure disclosed in Gough et al. '547 is not that of a device capable of transmitting or radiating microwave energy. The proximal portion of apparatus 10 does not contain a coaxial transmission line nor does the distal portion of apparatus 10 define a radiating portion.

Moreover, Gough et al. '547 does not disclose any cooling, fluid or otherwise. Thus, Gough et al. '547 can not disclose a fluid channel around the antenna or fluid in direct contact with the microwave antenna, as called for in claim 1.

d. U.S. Patent 6,496,737 to Rudie et al.

Rudie et al. '737 discloses a thermal therapy catheter that contains a microwave antenna 57 held in place within an antenna lumen 70 in the catheter by heat shrink tubing 87. (see Col. 4, lines 64-67). Heat shrink tubing 87 completely surrounds the microwave antenna 57. (see FIG. 7.) In addition, "antenna lumen 70 is sealed at a distal end by plugs 70A and 70B, forming cavity 86 therebetween." (see Col. 4, lines 59-61.).

In use, the thermal therapy catheter in Rudie et al. '737 is inserted into a body lumen or body cavity, such as, for example a vessel or artery of the vascular system or the urethra.

Rudie et al. '737 does not disclose a fluid channel around the antenna or fluid in direct contact with the microwave antenna, as called for in claim 1.

5. Arguments

Applicants respectfully submit that it would not have been obvious to one of ordinary skill in the art, at the time the invention was made, to modify Storm '130 in view of Edwards '755 and further in view of Gough et al '547 and even further in view of Rudie et al. '737 in order to arrive at claim 1 of the present application and thus render claim 1 obvious in view thereof.

As discussed above, the Examiner relies on Storm '130 for the disclosure of a cooling system for use with a microwave antenna (see Office Action of Oct. 26, 2006, page 4, line 12); on Edwards '755 for the disclosure of an introducer for use with a microwave antenna (see Office Action of Oct. 26, 2006, page 3, line 1); on Gough et al. '547 for the disclosure of a percutaneously advanceable microwave antenna (see Office Action of Oct. 26, 2006, page 3, lines 10-11); and on Rudie et al. '737 for the disclosure of a microwave antenna in direct connection (permitting a direct cooling effect of the antenna) with cooling fluid that is encapsulated by a cooling jacket 32 (see Office Action of Oct. 26, 2006, page 3, lines 12-15).

**a. The Prior Art Reference(s) Must
 Teach or Suggest All the Claim Limitations**

Applicants respectfully submit that none of the references of record, taken alone or in any proper combination, teach or suggest a cooling system for use with a microwave antenna, including, *inter alia*, a cooling jacket adapted to at least partially surround a microwave antenna and defining a fluid channel around at least a portion of the microwave antenna, wherein the cooling jacket is further adapted to circulate a cooling fluid through the fluid channel such that at least a portion of the microwave antenna is in direct fluid contact with the cooling fluid and wherein the microwave antenna comprises a distal tip configured to be advanced percutaneously through tissue, as recited in claim 1.

Applicants reiterate the arguments presented in Applicant's previous responses dated April 24, 2006, November 11, 2005, and May 13, 2005 in addition to the arguments presented below.

i. Cooling Limitation

Applicants respectfully submit that Storm '130, Edwards '755, Gough et al. '547 and Rudie et al. '737 fail to teach or suggest a microwave antenna comprising a cooling jacket adapted to at least partially surround a microwave antenna and defining a fluid channel around at least a portion of the microwave antenna.

Storm '130 discloses electrode means or structures 72 or 90 for electromagnetic radiational heating of tumor bearing tissue. The electrode means 72 or 90 are configured and adapted for **placement on an outer surface of the tissue** of the patient. The electrode means 72 or 90, as illustrated in FIGS. 1 and 2, covers an outer portion of the patient's skin (e.g., the thigh) with an emitting surface 21, 51 or 71. The emitting surface 21, 51 or 71 of Storm '130 comprises a large surface that covers a majority of a patient's thigh. (see FIGS. 3, 8, 9, 11 and 14). While Applicants concede that Storm '130 discloses a cooling system for use with a microwave antenna, Applicants respectfully submit that the overall structure in Storm '130 is so drastically different in configuration, design and size that individual elements in Storm '130 cannot be analogous to the elements recited in claim 1.

For example, the emitting surface in Storm '130 comprises a large surface that covers a majority of a patient's thigh while the radiating portion 12 of the present application is simply the distal portion of the apparatus.

Storm '130 further discloses the application of various cooling means to the back surface of the emitting surface including one or more cooling chambers 12, 44 or 44 and various

configurations of cooling coils 72 or 90 while the structure of present application includes a cooling jacket adapted to at least partially surround a microwave antenna and defining a fluid channel around at least a portion of the microwave antenna. Applicants submit that placing a large cooling chamber or cooling coils on the back surface of the emitting surface cannot possibly be analogous to the cooling structure of claim 1 of the present application.

Applicants submit that Edwards '755 teaches heating of the fluid in the expandable member. "Electrolytic solution in expandable member 12 is heated to a pre-selected temperature, which can be modified and adjusted as necessary." (see Col. 5, lines 18-21.) The electromagnetic delivery device heats the fluid in the chambers and the chambers heat and ablate the surrounding tissue.

Edwards '755 further recites the use of electrodes 28 and zones 30 that can be activated to ablate tissue. (see Col. 10, lines 11-12) In use, the semi-trapped electrolytic solution in zones 30 combines with electrode 28 to create a larger electrode. (see Col. 7, lines 19-21).

Applicants thus submit that if the solution is to be combined with the electrode 28 to create a larger electrode, then the electrolytic solution can not perform any cooling function, as called for in claim 1.

Therefore, Edwards '755 does not disclose a cooling system for use with a microwave antenna and may not be properly combined with Storm '130 to render present claim 1 obvious.

Applicants respectfully submit that Gough et al. '547 contains no reference to cooling whatsoever and thus no further discussion of Gough et al. '547 is warranted with regard to the

cooling limitation of claim 1, as presently presented. Therefore, Gough et al. '547 may not be properly combined with Storm '130 and/or Edwards '755 to render present claim 1 obvious.

Rudie et al. '737 discloses a thermal therapy catheter containing a microwave antenna 57 held in place within an antenna lumen 70 in the catheter by heat shrink tubing 87. (see Col. 4, lines 64-67). Applicant respectfully submits that Rudie et al. '737 does not disclose a cooling jacket adapted to at least partially surround a microwave antenna and defining a fluid channel around at least a portion of the microwave antenna, as recited in claim 1.

Thus, Rudie et al. '737 may not be properly combined with Storm '130 and/or Edwards '755 and/or Gough et al. '547 to render present claim 1 obvious.

iv. Direct Fluid Contact Limitation

Applicant respectfully submits that Storm '130, Edwards '755, Gough et al. '547 and Rudie et al. '737 fail to teach or suggest a microwave antenna such that at least a portion of the microwave antenna is in direct fluid contact with the cooling fluid, as recited in claim 1. Applicants respectfully traverse the Examiner assertion that Rudie et al '737 discloses this limitation.

As discussed above, Storm '130 discloses cooling chamber means 174 that surrounds radio frequency terminal post 73. Accordingly, the fluid carried by cooling chamber means 174 does not directly contact post 73.

In regards to Edwards '755, Applicants respectfully submit that if the device of Edwards '755 were modified to deliver "cooling" fluid to be in direct contact with electrodes 28 thereof,

that such a modification would destroy the utility of Edwards '755 because the fluid would act to draw heat away from electrodes 28 and not combined with the electrode 28 to create a larger electrode, as required by Edwards '755. Accordingly, the electrolytic fluid of Edwards '755 does not contact the microwave antenna for the purposes of cooling the same, as called for in claim 1.

Thus, Edwards '755 may not be properly combined with Storm '130 to render present claim 1 obvious.

Gough et al. '547 fails to disclose any form of cooling and thus fails to show, teach or disclose a fluid channel around the microwave antenna that is in direct fluid contact therewith, as called for in claim 1.

Thus, Gough et al. '547 may not be properly combined with Storm '130 and/or Edwards '755 to render present claim 1 obvious.

Rudie et al. '737 discloses a thermal therapy catheter that contains a microwave antenna 57 held in place within an antenna lumen 70 in the catheter by heat shrink tubing 87. (see Col. 4, lines 64-67). "Antenna lumen 70 is sealed at a distal end by plugs 70A and 70B, forming cavity 86 therebetween." (see Col. 4, lines 59-61.) Plugs 70A and 70B prevent fluid from entering the portion of the antenna lumen that contains the microwave antenna therefore the microwave antenna does not make direct fluid contact with the cooling fluid. In addition, heat shrink tubing 87 completely surrounds the microwave antenna 57 (see FIG. 7) thereby forming a second layer that prevents direct contact between the microwave antenna and the cooling fluid.

Thus, Rudie et al. '737 may not be properly combined with Storm '130 and/or Edwards '755 and/or Gough et al. '547 to render present claim 1 obvious.

Therefore, Applicants respectfully submit that Storm '130, Edwards '755, Gough et al. '547 and Rudie et al. '737 fail to teach or suggest a microwave antenna such that at least a portion of the microwave antenna is in direct fluid contact with the cooling fluid, as recited in claim 1.

**b. The Combined References Would Not
Have A Reasonable Expectation of Success**

Applicants respectfully submit that the combining of the teachings of Storm '130, Edwards '755, Gough et al. '547 and Rudie et al. '737 does not render claim 1 obvious.

Applicants further submit that combining the teachings of the four (4) references cited by the Examiner would require extensive experimentation and testing. Assuming arguendo, that even if the combination of the prior art references disclose all the limitations of claim 1 of the present application, the references cited by the Examiner could not be combined with a reasonable expectation of success in achieving claim 1 as presently presented.

**c. The References Do Not Contain Any
Suggestion or Motivation To Combine**

Applicants respectfully submit that there would have been no motivation to modify Storm '130, as suggested by the Examiner, to include the limitations lacking or missing therein. Storm '130 discloses a non-evasive device configured and adapted for placement on the outer surface of the tissue of the patient to treat internal tissue. Applicants respectfully submit that this is not a

situation were the mere substitution or addition of features to the disclosure of Storm '130, from the other cited references, would render claim 1 obvious. In contrast, the structure of Storm '130 would require a complete and total redesign, reconfiguration and/or reinvention in order to arrive at claim 1 of the present application.

Applicants respectfully submit that integrating or combining the disclosure of Storm '130 with the disclosures of Edwards '755, Gough et al. '547, and/or Rudie '737 is not obvious.

Applicants have not merely combined various features from the prior art, as suggested by the Examiner, in arriving at the present invention. Instead, Applicants have invented an entirely new, useful and non-obvious microwave antenna integrating a cooling system therewith. A further result of the invention is a microwave antenna, integrating a cooling system, that can be advanced percutaneously through tissue.

**d. The Examiner Must Then Consider Any
 Evidence Supporting the Patentability of the Claimed Invention**

As discussed hereinabove, Applicants respectfully submit that factual support has not been established for supporting a rejection for the claimed invention. If the Examiner believes that factual support has been established for rejecting the claimed invention under 35 U.S.C. §103(a), the Examiner must then consider any evidence supporting the patentability of the claimed invention.

Applicants respectfully submit that the evidence provided by hereinabove, in the specification, and in the previous responses supports a finding of patentability of the claimed invention.

6. Dependant Claims

Since claims 2-24 depend, directly or indirectly, from claim 1 and contain all of the limitations of claim 1, then for the reasons presented above regarding the patentability of claim 1, Applicants respectfully submit that claims 2-24 are also patentable over Storm '130 in view of Edwards '755 and further in view of Gough et al. '547 and even further in view of Rudie et al. '737.

Since claim 18 depends from claim 1 and contain all of the limitations of claim 1, then for the reasons presented above regarding the patentability of claim 1, Applicants respectfully submit that claim 18 is also patentable over Storm '130 in view of Edwards '755 and further in view of Gough et al. '547 and even further in view of Uthe '519 and further in view of Rudie et al. '737.

Since claim 17 depends from claim 1 and contain all of the limitations of claim 1, then for the reasons presented above regarding the patentability of claim 1, Applicants respectfully submit that claim 17 is also patentable over Storm '130 in view of Edwards '755 and further in view of Gough et al. '547 and even further in view of Edwards '217 and further in view of Rudie et al. '737.

7. Double Patenting

Claims 1-24 were provisionally rejected under the judicially created doctrine of obvious-type double patenting as being unpatentable over claims 25-45 and 64-77 of co-pending U.S. Application Serial No. 11/053,987. Upon information and belief, the present application and

Application Serial No. 11/053,987 are commonly owned. As such, upon the indication of allowability of the claims of the present application, except for the double patenting rejection, should the double patenting rejection remain following the present response, an appropriate terminal disclaimer will be submitted thereby obviating the rejection.

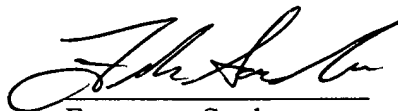
CONCLUSION

In view of the foregoing amendments and remarks, reconsideration of the application and allowance of claims 1-24 is earnestly solicited.

Should the Examiner believe that a telephone interview may facilitate prosecution of this application, the Examiner is respectfully requested to telephone Applicant's undersigned representative at the number indicated below.

Please charge any deficiency as well as any other fee(s) that may become due under 37 C.F.R. § 1.16 and/or 1.17 at any time during the pendency of this application, or credit any overpayment of such fee(s), to Deposit Account No. 21-0550.

Respectfully submitted.



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